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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/517,844	12/15/2004	Amnon Sintov	030231-0155	9004

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EXAMINER

AHMED, HASAN SYED

ART UNIT PAPER NUMBER

1615

DATE MAILED: 08/29/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/517,844

Applicant(s)

SINTOV, ET AL

Examiner

Hasan S. Ahmed

Art Unit

1615

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-12 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☒ Claim(s) 1-12 is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. ____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date 12/15/04.
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. ____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: ____.

DETAILED ACTION

Receipt is acknowledged of Applicants' IDS filed on 15 December 2004.

Priority

Receipt is acknowledged of papers submitted under 35 U.S.C. 119(a)-(d), which papers have been placed of record in the file.

Claim Objections

Claim 6 is objected to because of the following informality: "lidocaine" is spelled "lodocaine." Appropriate correction is required.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claim 5 recites the limitation "guar-based polymer." There is insufficient antecedent basis for this limitation in the claim from which it currently depends, claim 3. Proper antecedent basis for this limitation exists in claim 4.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

Claims 1-3, 6-8, 11 and 12 are rejected under 35 U.S.C. 102(a) as being anticipated by Luo, *et. al.* (U.S. Patent Application No. 2001/0051166).

Luo, *et. al.* disclose a transdermal or topical delivery system (see paragraph 0019). The disclosed transdermal or topical delivery system is the instant transdermal or topical delivery system as claimed:

- the transdermal delivery of local anesthetics of instant claim 1 (see paragraph 0069);
- the transdermal delivery of immunosuppressive agents of instant claim 1 (see paragraph 0063);
- the transdermal delivery of neurologically effective drugs of instant claim 1 (see paragraph 0063);
- the transdermal delivery of polypeptide (peptide) drugs of instant claim 1 (see paragraph 0063);
- the water-miscible tetraglycol of instant claim 1 (see Table 10);
- the hydrogel form of instant claim 1 (see paragraph 0153);
- the microemulsion (emulsion) of instant claim 1 (see paragraph 0136);
- the ionized polymer of instant claim 2 (see paragraph 0138);
- the acrylic polymer of instant claim 3 (see paragraph 0138);
- the granisetron of instant claim 6 (see paragraph 0070);
- the hydrogel patch of instant claim 7 (see paragraph 0153);
- the skin penetration (permeation) enhancer of instant claim 8 (see paragraph 0019);

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- the transdermal hydrogel comprising an alcohol-miscible drug combined with water-miscible tetraglycol and water of instant claim 11 (see paragraphs 0069, 0153 and Table 10);
- the topical delivery of local anesthetics of instant claim 12 (see paragraph 0002);
- the topical delivery of immunosuppressive agents of instant claim 12 (see paragraph 0063);
- the topical delivery of neurologically effective drugs of instant claim 12 (see paragraph 0063);
- the topical delivery of polypeptide (peptide) drugs of instant claim 12 (see paragraph 0063);
- the water-miscible tetraglycol of instant claim 12 (see Table 10);
- the hydrogel form of instant claim 12 (see paragraph 0153);
- the microemulsion (emulsion) of instant claim 12 (see paragraph 0136);

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

1. Claims 4 and 5 are rejected under 35 U.S.C. 103(a) as being unpatentable over Luo, *et. al* in view of Sintov, *et. al.* (WO 02 09763).

Luo, *et. al.* teach a transdermal or topical delivery system (see above).

Luo, *et. al.* explain that combining the disclosed agents into one transdermal/topical delivery system is beneficial because it leads to an enhanced "rate at which an active agent administered to a patient's body surface permeates into and/or through the body surface." See paragraph 0008.

The disclosed delivery system differs from the instant claims in that it does not disclose the guar-based polymer (instant claim 4) hydroxypropyl guar hydroxypropyltrimonium chloride (instant claim 5).

Sintov, *et. al.* teach a transdermal delivery system (see page 6) in hydrogel form (see page 7).

The disclosed hydrogel may comprise guar-based polymer hydroxypropyl guar hydroxypropyltrimonium chloride (see page 6).

It would have been obvious to a person of ordinary skill in the art at the time the invention was made to make a hydrogel based transdermal drug delivery system using the guar-based polymer hydroxypropyl guar hydroxypropyltrimonium chloride as taught by Luo, *et. al.* in view of Sintov, *et. al.* One of ordinary skill in the art at the time the invention was made would have been motivated to make such a drug delivery system to enhance transdermal drug delivery rates, as explained by Luo, *et. al.*

2. Claims 9 and 10 are rejected under 35 U.S.C. 103(a) as being unpatentable over Luo, *et. al.* in view of Sintov, *et. al.* (WO 02 09763).

Luo, *et. al.* teach a transdermal or topical delivery system (see above).

Luo, *et. al.* explain that combining the disclosed agents into one transdermal/topical delivery system is beneficial because it leads to an enhanced "rate at which an active agent administered to a patient's body surface permeates into and/or through the body surface." See paragraph 0008.

The disclosed delivery system differs from the instant claims in that it does not disclose a non-ionic surfactant (instant claim 9), such as sorbitan sesquioleate (instant claim 10), as a penetration enhancer.

Sintov, *et. al.* teach a transdermal delivery system (see page 6) in hydrogel form (see page 7).

The disclosed hydrogel may comprise a non-ionic surfactant, such as sorbitan sesquioleate, as a penetration enhancer (see page 7).

It would have been obvious to a person of ordinary skill in the art at the time the invention was made to make a hydrogel based transdermal drug delivery system using a non-ionic surfactant, such as sorbitan sesquioleate, as a penetration enhancer as taught by Luo, *et. al.* in view of Sintov, *et. al.* One of ordinary skill in the art at the time the invention was made would have been motivated to make such a drug delivery system to enhance transdermal drug delivery rates, as explained by Luo, *et. al.*

Double Patenting

Claims 1-12 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-12 of copending Application No. 10/343,008 ('008). Although the conflicting claims are not identical, they are not patentably distinct from each other because '008 teaches a

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transdermal delivery system in hydrogel form using water-miscible tetraglycol and water to dissolve drug (see claim 1).

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Correspondence

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Hasan S. Ahmed whose telephone number is 571-272-4792. The examiner can normally be reached on 9am - 5:30pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael P. Woodward can be reached on 571-272-8373. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.



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